

510(k) Summary

OCT - 3 2011

The 510(k) Summary is submitted in accordance with 21 CFR §807.92 and the requirements of the Safe Medical Device Act (SMDA) of 1990.

<u>Submitter's Name</u>	Abbott Vascular
<u>Submitter's Address</u>	3200 Lakeside Drive, Santa Clara, CA 95054
<u>Telephone</u>	(408) 845-0688
<u>Fax</u>	(408) 845-3743
<u>Contact Person</u>	Laarni Ricafort
<u>Date Prepared</u>	July 1, 2011
<u>Device Trade Name</u>	Armada 35 PTA Catheter Armada 35 LL PTA Catheter
<u>Device Common Name</u>	PTA Catheter
<u>Device Classification Name</u>	Catheter, angioplasty, peripheral, transluminal
<u>Predicate Device Names</u>	<ul style="list-style-type: none">• ev3 Inc's EverCross™ OTW PTA Dilatation Catheter (K110319, cleared 04/14/11)• Invatec Admiral XTREME™ PTA Balloon Dilatation Catheter (K100921, cleared 04/30/10)• Abbott Vascular's FoxCross PTA Catheter (K090509, cleared 03/20/09)

Device Description

The Armada 35/Armada 35 LL Percutaneous Transluminal Angioplasty (PTA) Catheter is a standard over-the-wire (OTW) balloon catheter to be used for percutaneous transluminal angioplasty (PTA). The dual-layer balloon (outer layer: Pebax L25, inner layer Pebax 7233D) will be available in lengths 20, 40, 60, 80, 100, 120, 150, 200 and 250 mm, with nominal diameters of 3, 4, 5, 6, 7, 8, 9, 10, 12 and 14mm. The balloon has a nominal diameter inflation pressure of 4, 6 and 8atm (depending on diameter) and a rated burst pressure between 7 to 28atm (depending on balloon size). Two swaged metal marker bands (PT/ IR) mark the working length of the balloons. The dual-lumen catheter shaft (Grilamid L25) has working lengths of 80 or 135 cm. The catheter shaft differs in outer diameter between 1.73 and 1.90 mm (depending on balloon size). One lumen is used for inflating the balloon and the second lumen allows access to the distal tip of the catheter for guide wire insertion. The inner member, which is constructed either of Grilamid L25 or ELG 6260 (depending on balloon size) will accept a 0.035" guide wire. The balloon, outer shaft of the catheter and the entire inner member is coated with silicone coating. The outer shaft has a polycarbonate y-arm luer adhesively bonded to the proximal end to allow for entry to the guide wire lumen and to allow for connection of the inflation device to the inflation/deflation lumen.

Indication for Use

The device is intended for dilatation of lesions in the renal, iliac, femoral, popliteal, tibial, and peroneal, arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

This device is also indicated for stent post-dilatation in the peripheral vasculature.

Technological Characteristics

Comparisons to the predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the current marketed predicate devices.

Performance Data

Performance testing was successfully completed on the Armada 35/35 LL PTA Catheter. The following tests were conducted:

- Balloon Preparation and Simulated Use (Trackability and Pushability)
- Balloon Preparation and Simulated Use (Withdrawal)
- Balloon Compliance (Diameter versus Pressure)
- Balloon Dimensions (Tip Entry Profile +1mm)
- Balloon Dimensions (Lesion Crossing Profile)
- Balloon Dimensions (Deflated Balloon Profile)
- Balloon Inflation/ Deflation Time
- Longitudinal Growth of Balloon
- Rated Burst Pressure (RBP)
- Balloon Fatigue
- RBP in Balloon-Expandable Stents
- RBP in Self-Expanding Stents
- Balloon Fatigue in Balloon-expandable Stent (Repeat Balloon Inflations in Stent)
- Balloon Fatigue in Self-expanding Stent (Repeat Balloon Inflations in Stent)
- Tensile strength distal balloon welding
- Tensile strength proximal balloon welding
- Tensile strength joint shaft/ manifold
- Withdrawal force through introducer sheath –short sheath
- Withdrawal force through introducer sheath –long sheath
- Catheter Pullback Force into Short Sheath After Reinsertion
- Catheter Pullback Force into Long Sheath After Reinsertion
- Guide wire Lumen Collapse
- Flexibility & Kink Test
- Torque strength
- Biocompatibility
 - Cytotoxicity – Qualitative (L929 MEM Elution Test– ISO)

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- Irritation – Intracutaneous Irritation -- ISO
- Sensitization study – Kligman Maximization Test – ISO
- Acute Systemic Toxicity – Systemic Injection Test –ISO
- Pyrogen Test – Material Mediated – ISO
- Hemolysis – Rabbit Blood – ASTM – Direct and Indirect Contact
- *In Vitro* Hemocompatibility Assay -- ISO, Indirect Contract
- Complement Activation Assay (C3a & SC5b9)
- Packaging and Sterilization Validation
- Shelf Life (Accelerated Aging)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Abbott Vascular
c/o Laarni Ricafort
Regulatory Affairs Associate
3200 Lakeside Drive
Santa Clara, CA 95054

OCT - 3 2011

Re: K111899
Trade/Device Name: Armada 35/35LL PTA Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: July 01, 2011
Received: July 05, 2011

Dear Ms. Ricafort:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

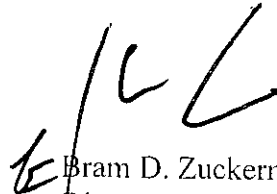
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', is written over a horizontal line.

Bram D. Zuckerman, M.D.
Director

Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111899

Device Names: Armada 35/Armada 35 LL PTA Catheter

Indications for Use: The device is intended for dilatation of lesions in the renal, iliac, femoral, popliteal, tibial, and peroneal, arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

This device is also indicated for stent post-dilatation in the peripheral vasculature.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

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